

AMENDED IN ASSEMBLY MARCH 5, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

**ASSEMBLY BILL**

**No. 103**

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**Introduced by Assembly ~~Member~~ Members Reyes and Koretz**  
**(Coauthors: Assembly Members Hancock and Lieber)**  
**(Coauthors: Senators Chesbro, Romero, and Soto)**

January 10, 2003

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An act to add Section 4168 to the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 103, as amended, Reyes. Pharmaceuticals: marketing activities.

Existing law, the Pharmacy Law, regulates wholesalers and manufacturers of dangerous drugs and makes the California State Board of Pharmacy responsible for administering and enforcing the provisions of that law. Under the Pharmacy Law, all revenue collected by the board is deposited into the Pharmacy Board Contingent Fund. The Pharmacy Law makes a violation of its provisions punishable as a crime.

This bill would require a pharmaceutical manufacturing company, as defined, to annually disclose to the board *certain information regarding the economic benefits the company provides in connection with its marketing activities, including disclosing the names of the recipients of any benefits and the value, nature, and purpose of the benefits*. The bill would also require the board to report annually to the Governor and the Legislature regarding these disclosures.

The bill would impose a civil penalty of \$10,000 for the violation of its disclosure requirements and would specify that awards obtained by the board be deposited into the Pharmacy Board Contingent Fund.

The bill by specifying an additional requirement under the Pharmacy Law, the violation of which is punishable as a criminal offense, would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 4168 is added to the Business and  
2 Professions Code, to read:

3 4168. (a) On or before January 1 of each year, a  
4 pharmaceutical manufacturing company shall disclose to the  
5 board the *recipient name and* value, nature, and purpose of any  
6 gift, fee, payment, subsidy, or other economic benefit it provided  
7 directly or through its pharmaceutical marketers *or wholesale*  
8 *distributors* in connection with detailing, promotional, or other  
9 marketing activities to a physician, hospital, nursing home,  
10 pharmacist, health benefit plan administrator, or any other person  
11 in California authorized to prescribe, dispense, or purchase  
12 dangerous drugs in this state. Disclosure shall be made on a form  
13 and in a manner prescribed by the board. The initial disclosure  
14 shall be made on or before January 1, 2005, for the period  
15 beginning on July 1, 2003, and ending June 30, 2004. The board  
16 shall report to the Governor and the Legislature on or before March  
17 1 of each year, commencing in 2006, the information disclosed to  
18 it pursuant to this section.

19 (b) A pharmaceutical manufacturing company shall also  
20 disclose to the board, on or before October 1, 2004, and annually  
21 thereafter, the name and address of the individual responsible for  
22 the company's compliance with the provisions of this section.



1 (c) The board shall not disclose information identified as a  
2 trade secret by the pharmaceutical marketing company in its  
3 disclosure.

4 (d) The following shall be exempt from disclosure:

5 (1) A complimentary sample of a dangerous drug intended to  
6 be furnished to a patient.

7 (2) The payment of reasonable compensation and  
8 reimbursement of expenses in connection with a clinical trial.

9 (3) Any gift, fee, payment, subsidy, or other economic benefit  
10 having a value of less than twenty-five dollars (\$25).

11 ~~(4) A scholarship or other support for medical students,~~  
12 ~~residents, and fellows to attend a significant educational,~~  
13 ~~scientific, or policymaking conference of a national, regional, or~~  
14 ~~specialty medical or other professional association, if the recipient~~  
15 ~~of the scholarship or other support is selected by the association.~~

16 (e) A civil penalty in the amount of ten thousand dollars  
17 (\$10,000) may be assessed for each violation of this section. Each  
18 failure to disclose constitutes a separate violation of this section for  
19 which the civil penalty may be assessed. The prevailing plaintiff  
20 in the action shall be awarded costs and reasonable attorney's fees  
21 in addition to the civil penalty. If the board is the prevailing  
22 plaintiff, the civil penalty, costs, and attorney's fees shall be  
23 deposited into the Pharmacy Board Contingent Fund.

24 (f) The following definitions apply for purposes of this section:

25 (1) "Clinical trial" means an approved clinical trial conducted  
26 in connection with a research study designed to answer specific  
27 questions about vaccines, new therapies, or new ways of using  
28 known treatments.

29 (2) "Pharmaceutical manufacturing company" means an  
30 entity that is engaged in the production, preparation, propagation,  
31 compounding, conversion, or processing of dangerous drugs,  
32 either directly, or indirectly, by extraction from substances of  
33 natural origin or independently by means of chemical synthesis or  
34 by a combination of extraction and chemical synthesis  
35 "Pharmaceutical manufacturing company" also means an entity  
36 engaged in the packaging, repackaging, labeling, relabeling, or  
37 distribution of dangerous drugs.

38 (3) "Pharmaceutical marketer" means a person who, while  
39 employed by or under contract to represent a pharmaceutical  
40 manufacturing company, engages in pharmaceutical detailing,

1 promotional activities, or other marketing of a dangerous drug in  
2 this state to a physician, hospital, nursing home, pharmacist, health  
3 benefit plan administrator, or any other person authorized to  
4 prescribe, dispense, or purchase a dangerous drug. ~~The term does~~  
5 ~~not include a wholesale drug distributor or the distributor's~~  
6 ~~representative who promotes or otherwise markets the services of~~  
7 ~~the wholesale drug distributor in connection with a dangerous~~  
8 ~~drug.~~

9 SEC. 2. No reimbursement is required by this act pursuant to  
10 Section 6 of Article XIII B of the California Constitution because  
11 the only costs that may be incurred by a local agency or school  
12 district will be incurred because this act creates a new crime or  
13 infraction, eliminates a crime or infraction, or changes the penalty  
14 for a crime or infraction, within the meaning of Section 17556 of  
15 the Government Code, or changes the definition of a crime within  
16 the meaning of Section 6 of Article XIII B of the California  
17 Constitution.

